Overview of Draft Exposure Summaries

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Presentation Outline

1) What are exposure summaries?

2) Why do we need exposure summaries?

3) Overview of exposure summaries

What Are Exposure Summaries?

- **Standard but flexible formats or templates that can be used for summarizing and presenting exposure assessment results**
- **Provide a road map and a snapshot for exposures**
- **Characterize the completeness and quality of the exposure assessment results**

Why Do We Need Exposure Summaries?

- A need for consistency in reporting exposure information
- A consistent format will allow readers to more easily find information
- A consistent format can help exposure assessors/preparers
- It is important to characterize the completeness and quality of the exposure assessment results in a transparent manner
- EPA will work with stakeholders to develop a template…“robust summaries” - FR Notice

Exposure Summaries

Summary 1:	**General Information**
Summary 2:	**Summary of Release and Exposure**
Summary 3:	**Summary of Monitoring Evaluations**
Summary 4:	**Summary of Modeling Evaluations**

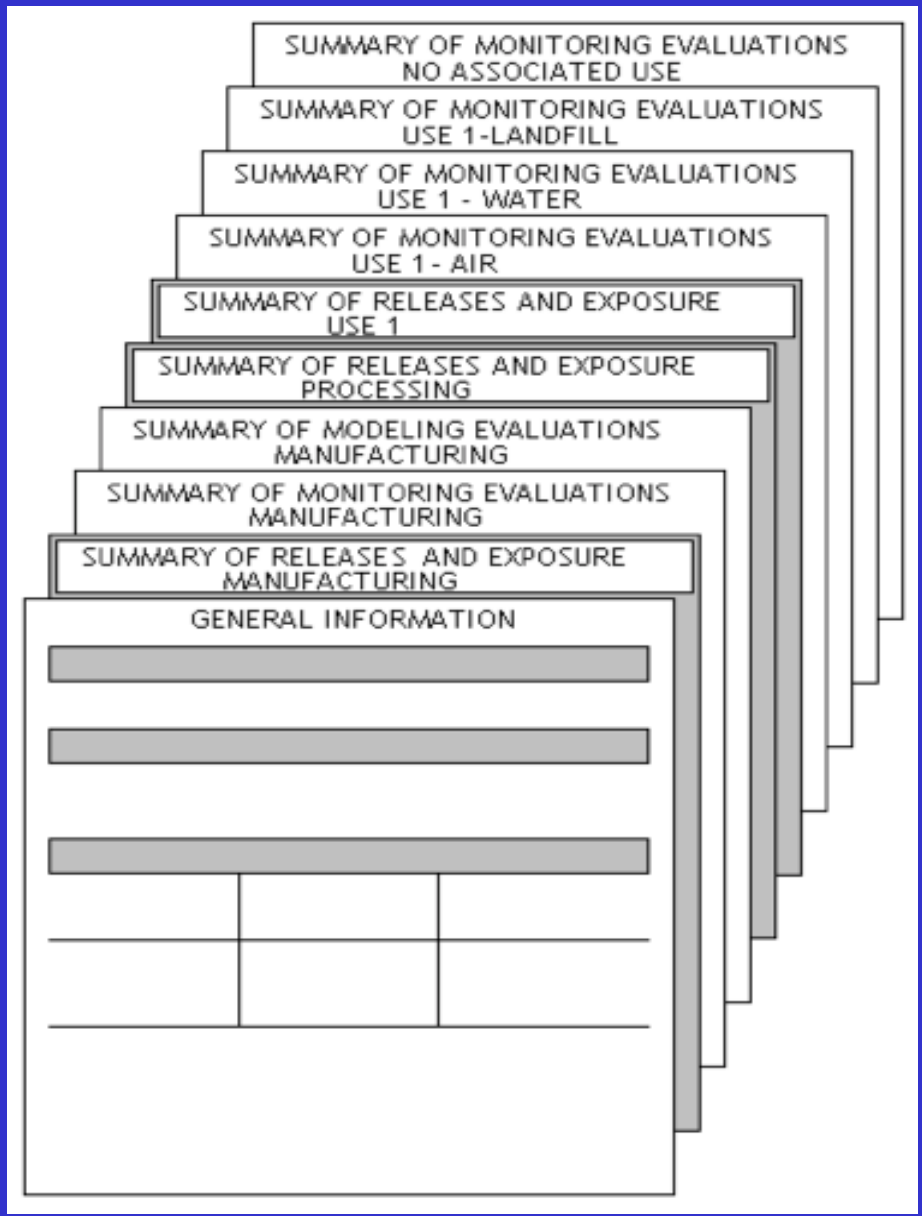


Figure 2. Example of Exposure Formats in a Complete Submission

- **Nested format of summaries**
- **Individual monitoring and modeling evaluations follow the exposure and release summary for each activity**

Overview of Exposure Summaries

Summary 1: General Information

(page 1)

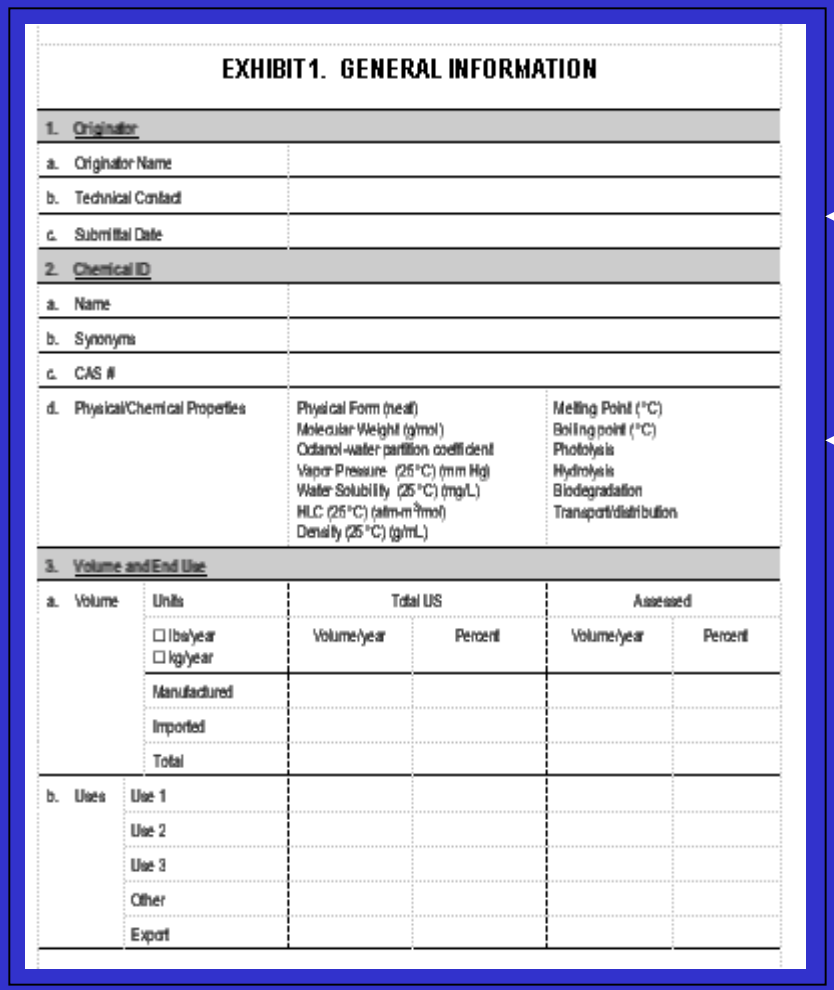


EXHIBIT 1. GENERAL INFORMATION

1. Originator					
a. Originator Name					
b. Technical Contact					
c. Submittal Date					
2. Chemical ID					
a. Name					
b. Synonyms					
c. CAS #					
d. Physical/Chemical Properties	Physical Form (neat) Molecular Weight (g/mol) Octanol-water partition coefficient Vapor Pressure (25°C) (mm Hg) Water Solubility (25°C) (mg/L) HLC (25°C) (atm-m³/mol) Density (25°C) (g/mL)		Melting Point (°C) Boiling point (°C) Photolysis Hydrolysis Biodegradation Transport/distribution		
3. Volume and End Use					
a. Volume	Units	Total US		Assessed	
	☐ lbs/year ☐ kg/year	Volume/year	Percent	Volume/year	Percent
	Manufactured				
	Imported				
	Total				
b. Uses	Use 1				
	Use 2				
	Use 3				
	Other				
	Export				

Originator Identification

Chemical Identification & Properties

Volume and End Use Data

Overview of Exposure Summaries

Summary 1: General Information

(page 2)

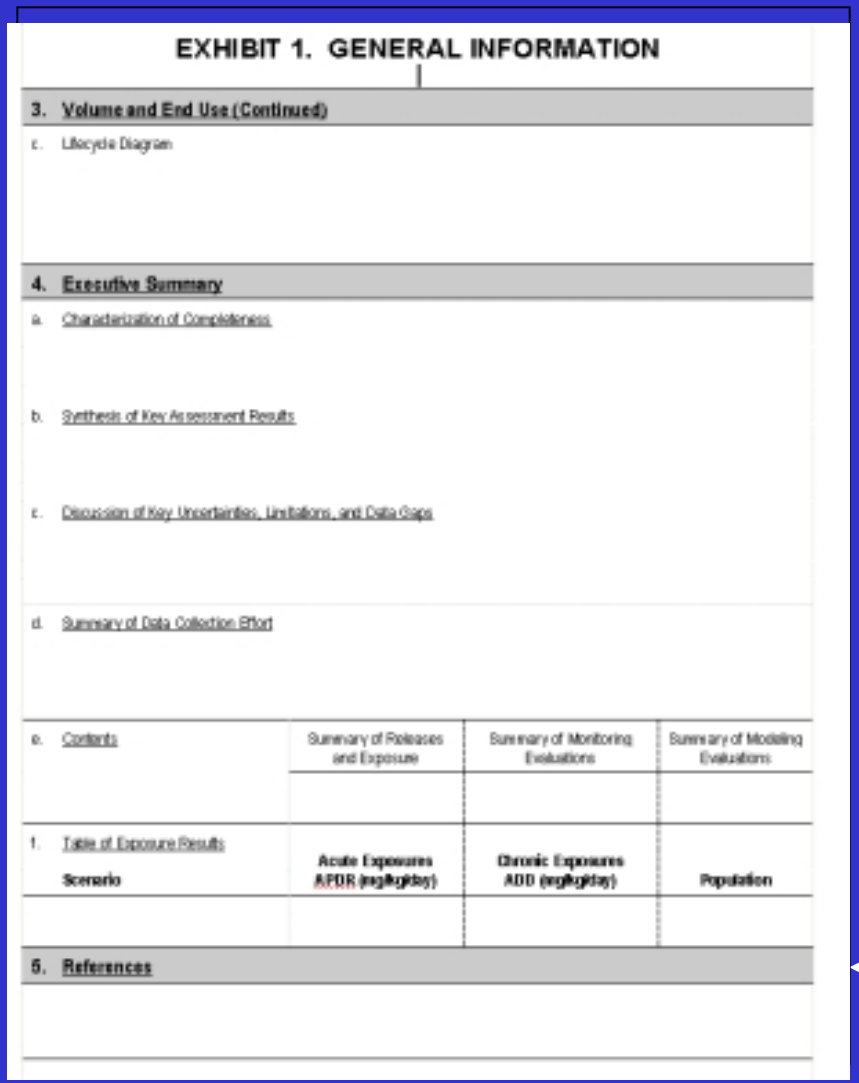


EXHIBIT 1. GENERAL INFORMATION

3. Volume and End Use (Continued)

c. Lifecycle Diagram

4. Executive Summary

a. Characterization of Completeness

b. Synthesis of Key Assessment Results

c. Discussion of Key Uncertainties, Limitations, and Data Gaps

d. Summary of Data Collection Effort

e. Contents	Summary of Releases and Exposure	Summary of Monitoring Evaluations	Summary of Modeling Evaluations

f. Table of Exposure Results Scenario	Acute Exposures ADDR (mg/kg/day)	Chronic Exposures ADD (mg/kg/day)	Population

5. References

Lifecycle Diagram

Executive Summary

References

Summary 1. General Information
Section 3. Volume and End Use

a. **Volume**
   - Specify what % of the covered volume is assessed.
   - The goal is to account for 100% of the covered production/import volume.

b. **Uses**
   - Describe the uses of the chemical and associated volume.
   - Include as many entries as possible to account for all of the production volume assessed.

Summary1. General Information Section 4. Executive Summary

a. Characterization of Completeness

- Characterize how completely the chemical volumes cited in Section 3 were accounted for.
- If not all volume is accounted for, provide an explanation.
- Describe exposure associated with each activity listed in Section 3.
- Identify exposure scenarios assessed. For those not assessed, provide an explanation.

Summary 1. General Information
Section 4. Executive Summary (cont.)

b. Synthesis of Key Assessment Results

- **Summarize the results of the exposure assessment.**

c. Discussion of Key Uncertainties, Limitations, and Data Gaps

- **Often 100% of total PV cannot be tracked. When this occurs, identify these limitations and the uncertainties that may stem from them.**
- **List data gaps not already covered under 4a.**

Summary 1. General Information
Section 4. Executive Summary (cont.)

d. Data Collection Effort

- Provide a narrative of efforts involved in researching and collecting data.
- Indicate if this exposures summary includes all of the monitoring data that were found or collected. If not, why?

e. Contents

- List the release and exposure formats and associated modeling and monitoring evaluations formats.

f. Table of Exposure Results

Overview of Exposure Summaries

Summary 2: Summary of Releases & Exposure (page 1)

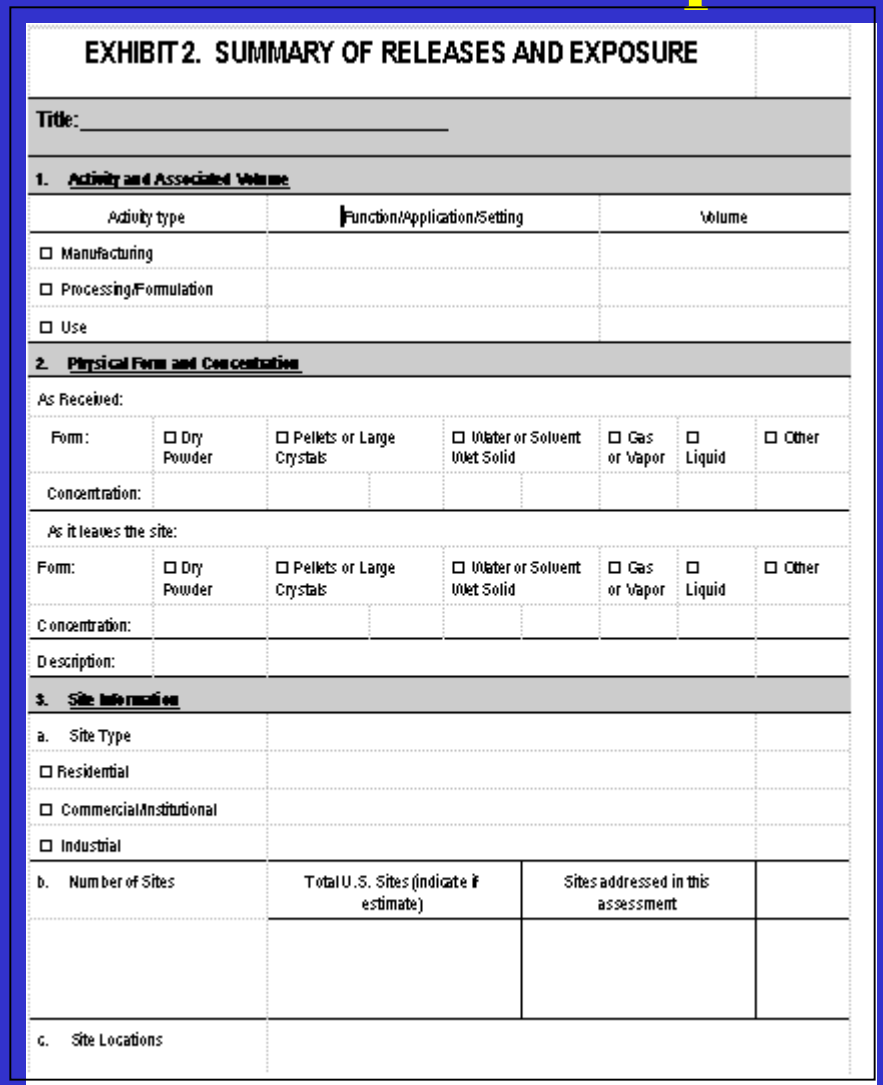


EXHIBIT 2. SUMMARY OF RELEASES AND EXPOSURE

Title: _____

1. Activity and Associated Volume

Activity type	Function/Application/Setting	Volume
☐ Manufacturing		
☐ Processing/Formulation		
☐ Use		

2. Physical Form and Concentration

As Received:

Form:	☐ Dry Powder	☐ Pellets or Large Crystals	☐ Water or Solvent Wet Solid	☐ Gas or Vapor	☐ Liquid	☐ Other
Concentration:						

As it leaves the site:

Form:	☐ Dry Powder	☐ Pellets or Large Crystals	☐ Water or Solvent Wet Solid	☐ Gas or Vapor	☐ Liquid	☐ Other
Concentration:						
Description:						

3. Site Information

a. Site Type

☐ Residential

☐ Commercial/Institutional

☐ Industrial

b. Number of Sites	Total U.S. Sites (indicate if estimate)	Sites addressed in this assessment	

c. Site Locations

Activity and Associated Volume

Physical Form and Concentration

Site Information

Summary 2: Summary of Releases & Exposure (page 2)

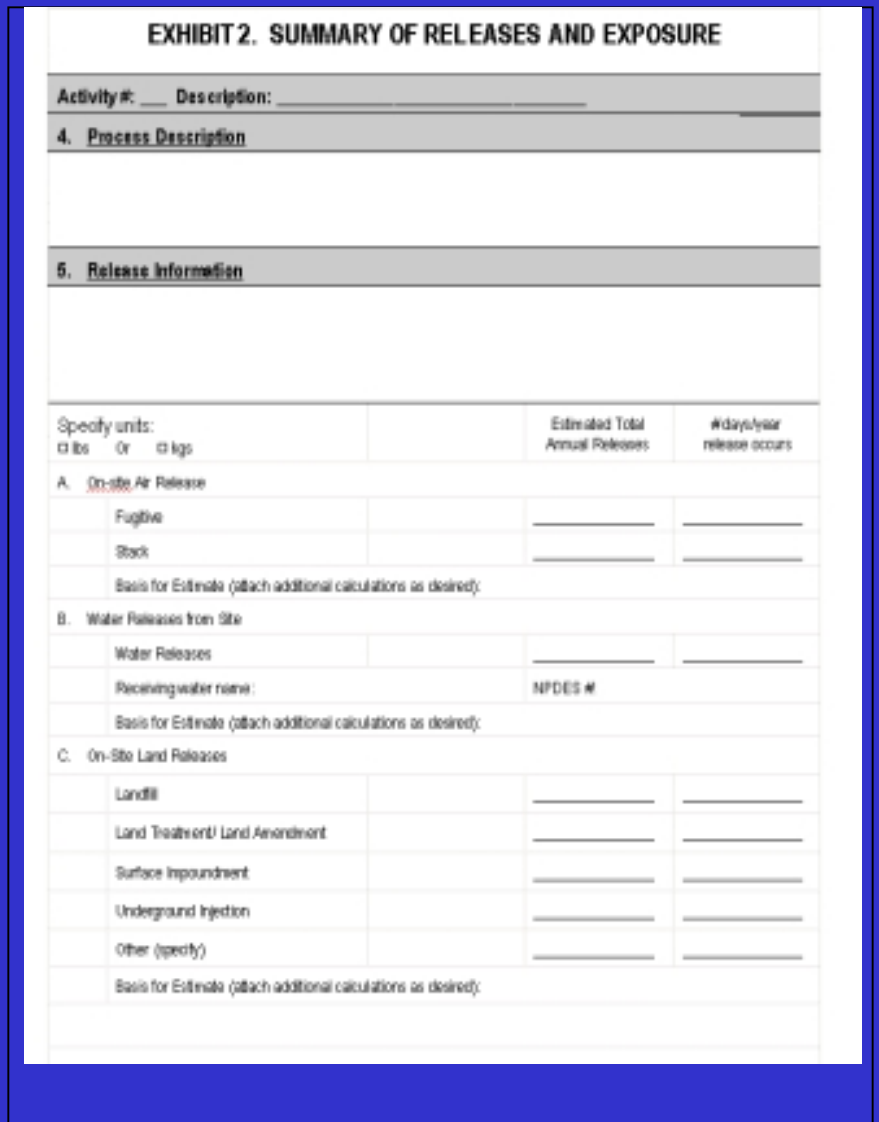


EXHIBIT 2. SUMMARY OF RELEASES AND EXPOSURE

Activity #: ___ Description: _____

4. Process Description

5. Release Information

Specify units: ☐ lbs ☐ or ☐ kgs		Estimated Total Annual Releases	#days/year release occurs
A. On-site Air Release			
Fugitive		_____	_____
Stack		_____	_____
Basis for Estimate (attach additional calculations as desired):			
B. Water Releases from Site			
Water Releases		_____	_____
Receiving water name:		NPDES #	
Basis for Estimate (attach additional calculations as desired):			
C. On-Site Land Releases			
Landfill		_____	_____
Land Treatment/ Land Amendment		_____	_____
Surface Impoundment		_____	_____
Underground Injection		_____	_____
Other (specify)		_____	_____
Basis for Estimate (attach additional calculations as desired):			

Process Description

Release Information:

A. Air

B. Water

C. Land

Summary 2: Summary of Releases & Exposure (page 3)

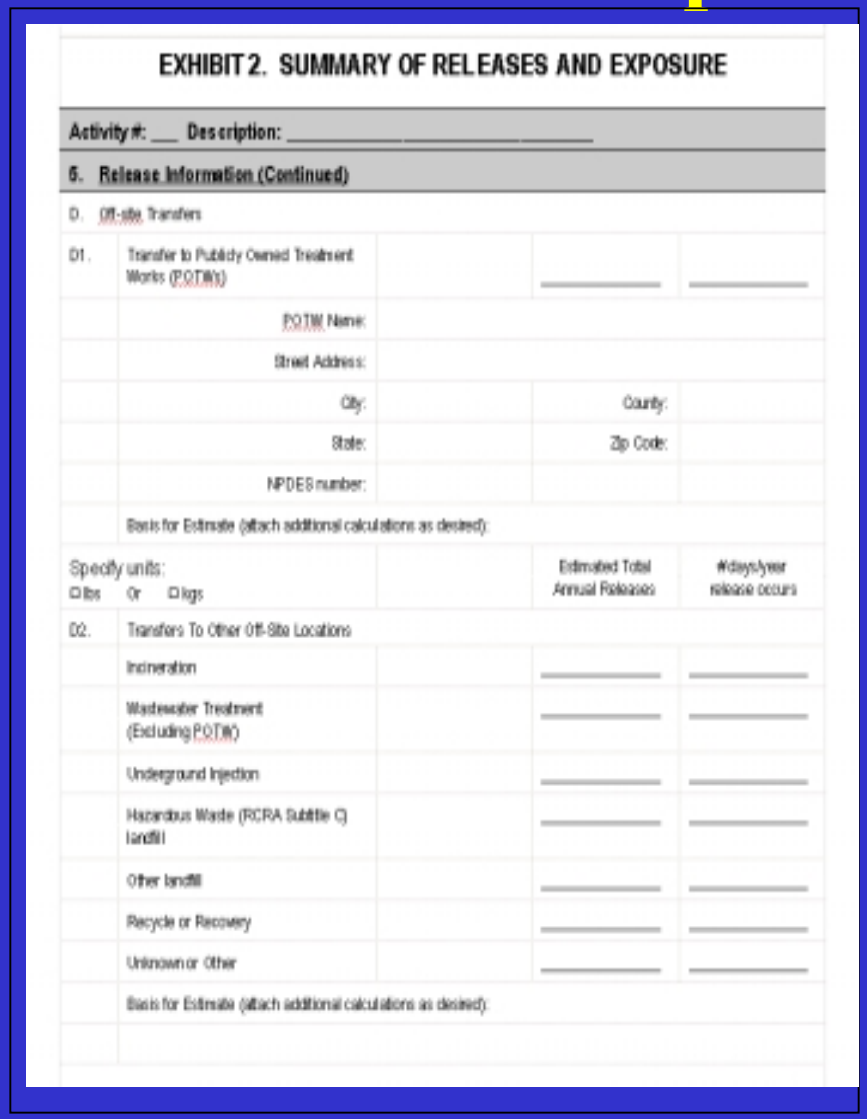


EXHIBIT 2. SUMMARY OF RELEASES AND EXPOSURE

Activity #: ___ Description: _____

6. Release Information (Continued)

D. Off-site Transfers

D1.	Transfer to Publicly Owned Treatment Works (POTW's)		_____	_____
	POTW Name:			
	Street Address:			
	City:		County:	
	State:		Zip Code:	
	NPDES number:			
	Basis for Estimate (attach additional calculations as desired)			
	Specify units: ☐lbs Or ☐kgs		Estimated Total Annual Releases	#days/year release occurs
D2.	Transfers To Other Off-Site Locations			
	Incineration		_____	_____
	Wastewater Treatment (Excluding POTW)		_____	_____
	Underground Injection		_____	_____
	Hazardous Waste (RCRA Subtitle C) landfill		_____	_____
	Other landfill		_____	_____
	Recycle or Recovery		_____	_____
	Unknown or Other		_____	_____
	Basis for Estimate (attach additional calculations as desired)			

Release Information (continued):

D. Transfers

Overview of Exposure Summaries

Summary 2: Summary of Releases & Exposure (page 4)

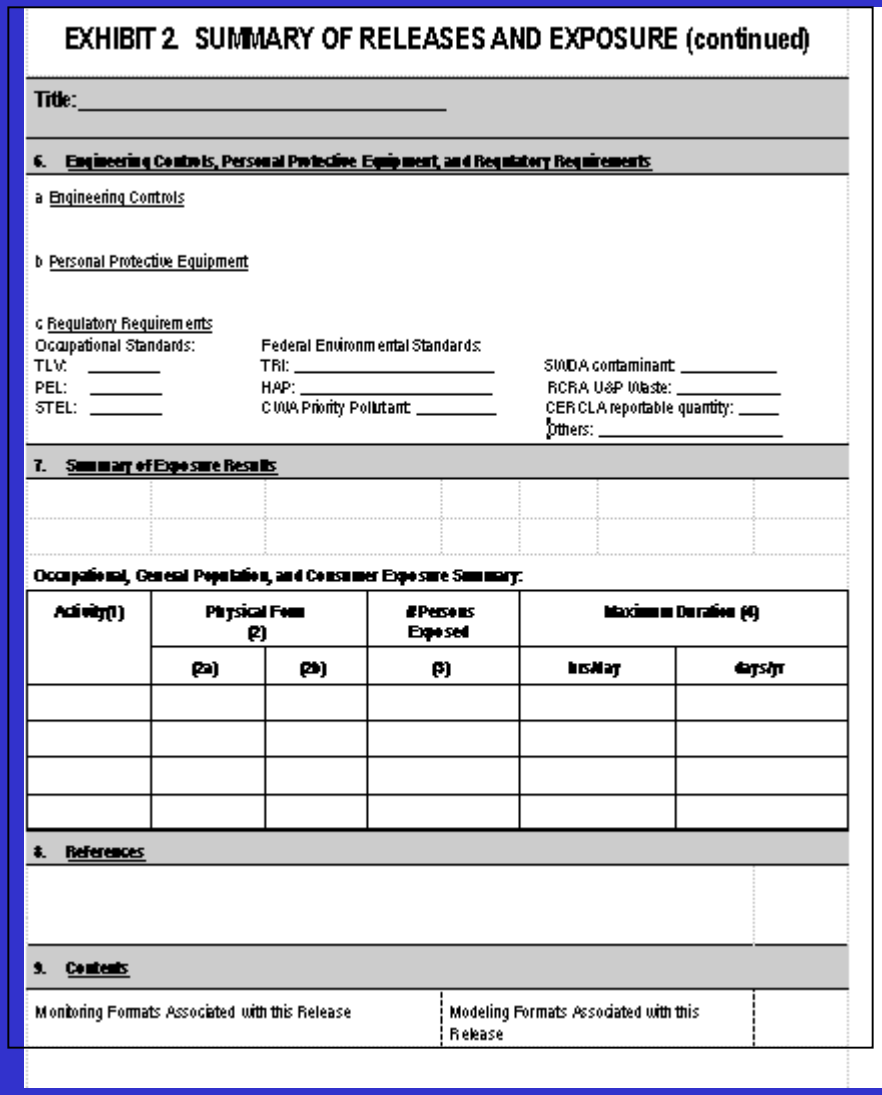


EXHIBIT 2. SUMMARY OF RELEASES AND EXPOSURE (continued)

Title: _____

6. Engineering Controls, Personal Protective Equipment, and Regulatory Requirements

a Engineering Controls

b Personal Protective Equipment

c Regulatory Requirements

Occupational Standards:
TLV: _____
PEL: _____
STEL: _____

Federal Environmental Standards:
TRI: _____
HAP: _____
CWA Priority Pollutant: _____

SWDA contaminant: _____
RCRA U&P Waste: _____
CERCLA reportable quantity: _____
Others: _____

7. Summary of Exposure Results

Occupational, General Population, and Consumer Exposure Summary:

Activity(1)	Physical Form (2)		# Persons Exposed	Maximum Duration (4)	
	(2a)	(2b)	(3)	hrs/day	days/yr

8. References

9. Contents

Monitoring Formats Associated with this Release	Modeling Formats Associated with this Release	

- Engineering Controls
- Personal Protective Equipment, and
- Regulatory Limits

→ Summary of Exposure Results

→ References

→ Contents of Submission

Summary 2. Summary of Releases & Exposures
Section 5. Release Information

- Specify the environmental releases (to all media) for each activity (manufacturing, processing, and use).
- Be as quantitative and precise as possible.
- Avoid the use of words such as significant, negligible.

Summary 2. Summary of Releases & Exposures
Section 7. Summary of Exposure Results

- Provide a summary of the exposure assessment results that are associated with the activity.
- Present in more detail in attached formats for exposure estimates based on monitoring data and those based on models.
- If exposure for an activity is not described, provide explanation.

Summary 3: Summary of Monitoring Evaluations

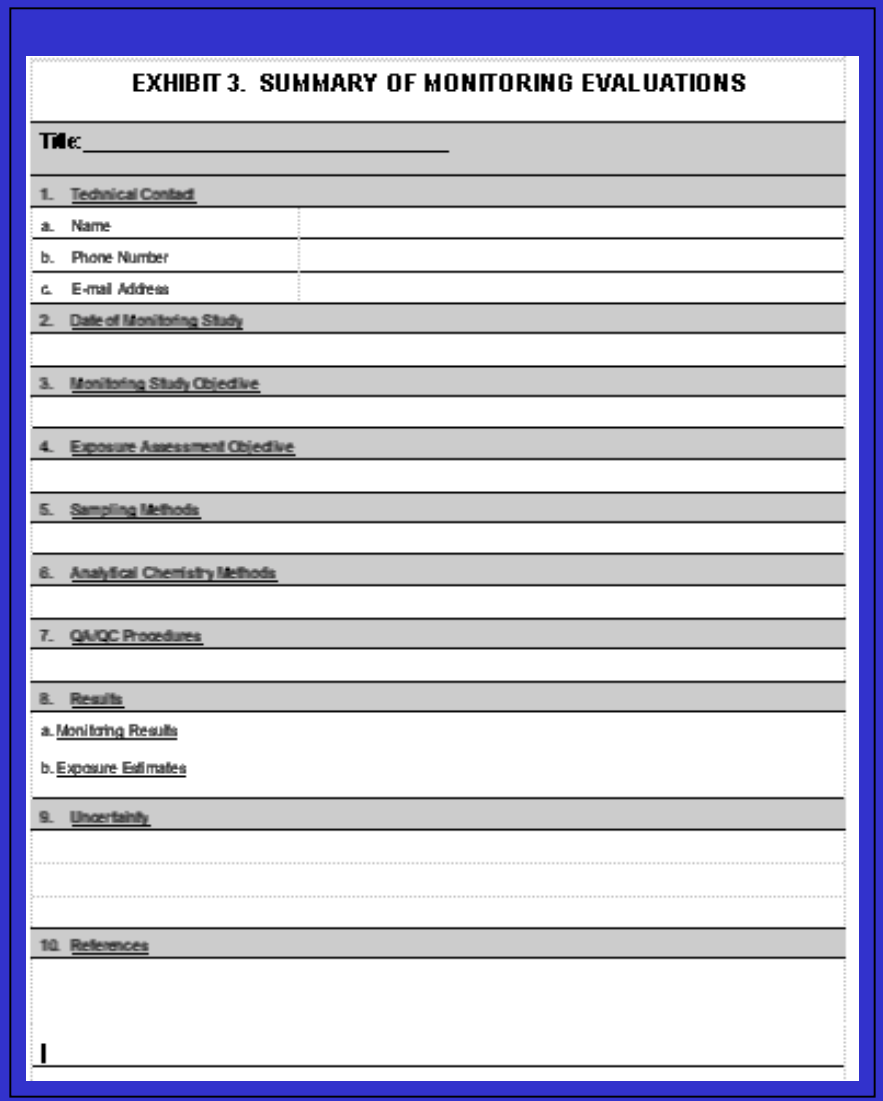


EXHIBIT 3. SUMMARY OF MONITORING EVALUATIONS

Title: _____

1. Technical Contact
   a. Name
   b. Phone Number
   c. E-mail Address
2. Date of Monitoring Study
3. Monitoring Study Objective
4. Exposure Assessment Objective
5. Sampling Methods
6. Analytical Chemistry Methods
7. QA/QC Procedures
8. Results
   a. Monitoring Results
   b. Exposure Estimates
9. Uncertainty
10. References

Monitoring Study Basic Information

Results & Uncertainty

References

Summary 4: Summary of Modeling Evaluations

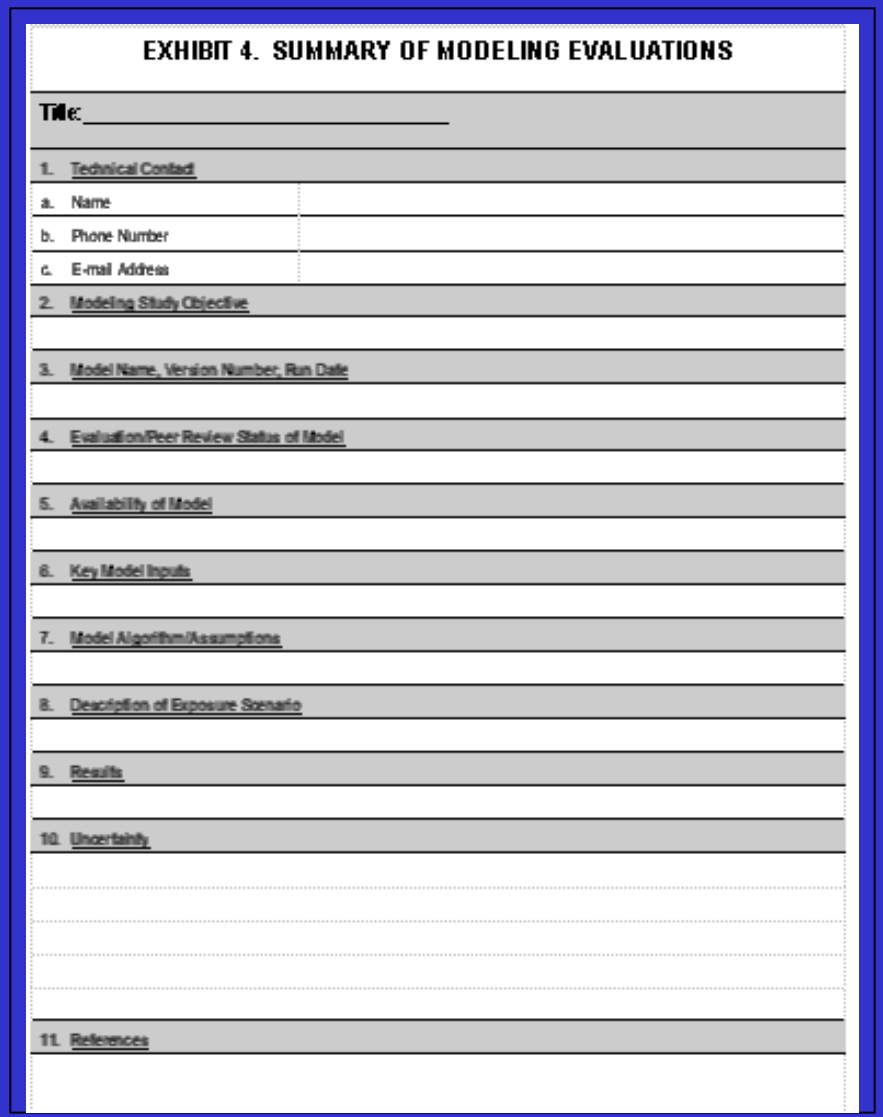


EXHIBIT 4. SUMMARY OF MODELING EVALUATIONS

Title: _____

1. Technical Contact
   a. Name
   b. Phone Number
   c. E-mail Address
2. Modeling Study Objective
3. Model Name, Version Number, Run Date
4. Evaluation/Peer Review Status of Model
5. Availability of Model
6. Key Model Inputs
7. Model Algorithm/Assumptions
8. Description of Exposure Scenario
9. Results
10. Uncertainty
11. References

Modeling Study Basic Information

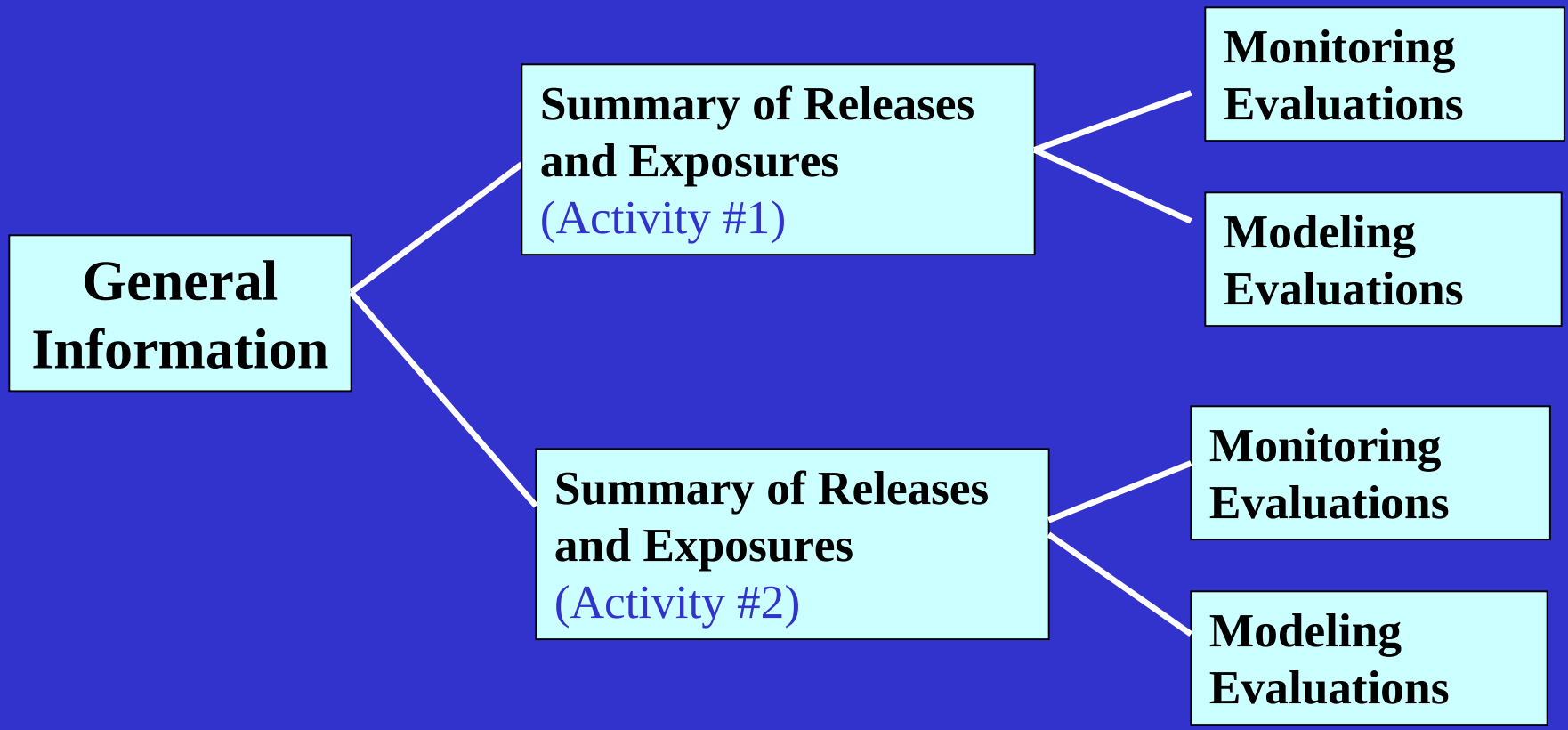
Results & Uncertainty

References

Summaries 3 & 4. Summary of Monitoring/Modeling Evaluations

- Provide supporting documentation for exposure data
- A summary should be completed for each study conducted or identified.
- Information should enable a user to duplicate the assessment results or able to find same results in reference section.

Exposure Summaries



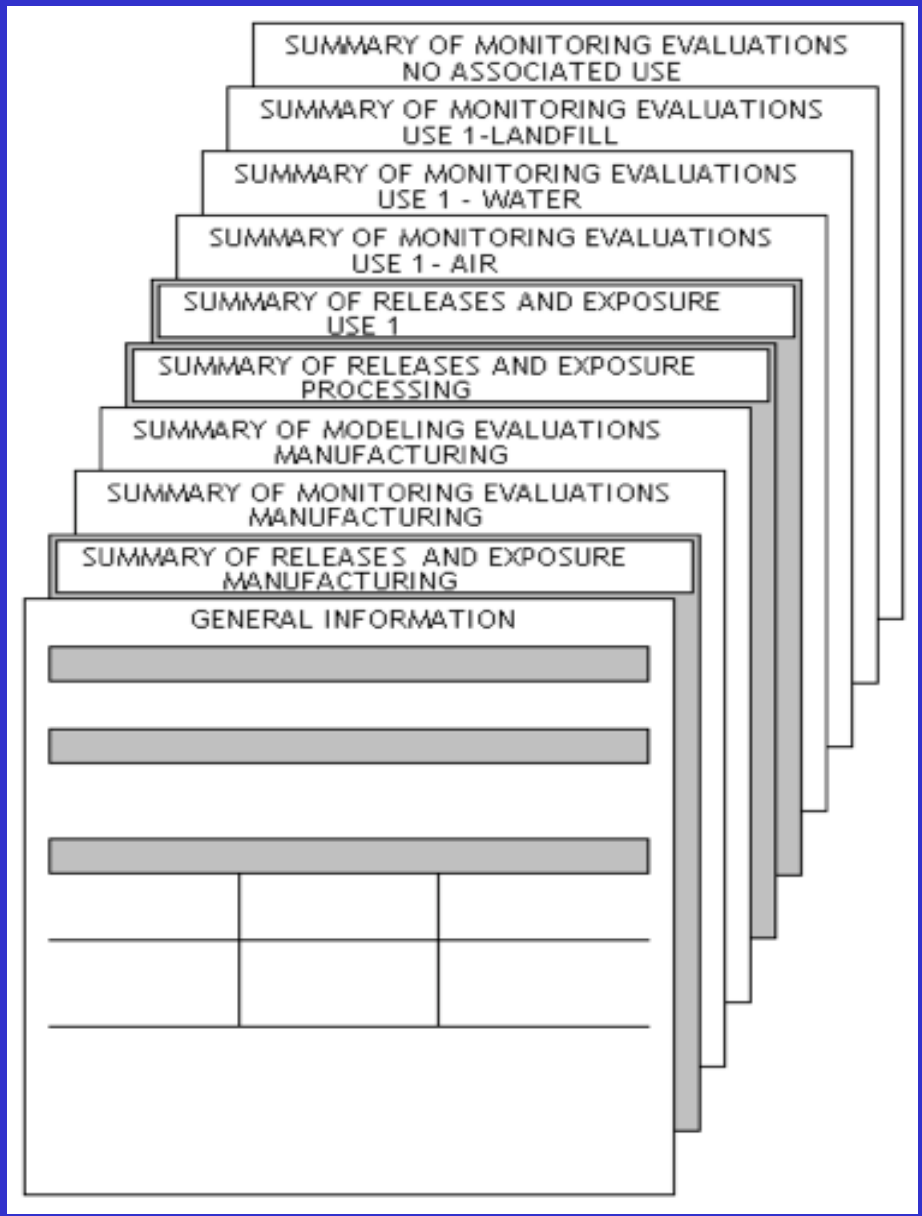


Figure 2. Example of Exposure Formats in a Complete Submission

- **Nested format of summaries**
- **Individual monitoring and modeling evaluations follow the exposure and release summary for each activity**

Summary

- A need for a consistent format in reporting
- Standard but flexible summary formats will promote consistency in reporting results and ease in reviewing the results
- Exposure summaries should characterize the completeness and quality of the exposure assessment results in a transparent manner
- Work In Progress
- Can be used as a template for presenting exposure information